

REMARKS

Claims 1-10 and 12 are all the claims which have been examined. Claims 1, 9, and 10 are the only independent claims. By this Amendment, Applicant adds new claim 13. Hence, claims 1-10 and 12-13 are all the claims pending in the Application.

Claim Rejections - 35 U.S.C. § 102

Claims 1-6 and 10 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Hegwood (US Patent 6,668,831). Applicant respectfully traverses.

The Examiner asserts that Hegwood discloses a tracheostomy cannula mounting comprising a planar sheet 2.13 (i.e. made in accordance with sheet 13, see also col. 8, lines 30-36) with an associated channel (see aperture 2.15) wherein the sheet includes an adhesive layer that is comprised of tacky gel-type materials such as gum, etc. In regard to claim 10, the Examiner asserts that the method as claimed would be inherent during normal use and operation of the device.

Applicant submits that, contrary to the Examiner's assertion, Hegwood does not disclose the use of a sheet "wherein material from which the sheet is fabricated comprises tacky gel material at least in the vicinity of the mounting face," as recited in claims 1 and 10. Hegwood discloses, in relevant part, "a sheet 17 of waterproof or substantially waterproof material (i.e. any plastic or the like typically used for medical dressings...) having an adhesive coating 19 at least partially covering one side for secure attachment to the patient's skin. The protective cover 13 may include a cushion 20 surrounding the aperture 15. A portion (of the - sic) adhesive coating 19 may be provided on the outer side of the cushion 20." See col. 5, line 5-15.

As the present specification explains at page 3, lines 13-21, it is known in the prior art to use an adhesive material between the skin and the cannula in order to obtain a better seal. However, the present specification also explains that this method requires frequent changing of the adhesive and may cause irritation to sensitive skin. Applicant submits that the claimed invention overcomes these problems by using a sheet made of a material comprising tacky gel, which is different from standard medical adhesive. See present specification at page 4, lines 25-30.

In comparison, Hegwood uses an adhesive to secure a separate, non-adhesive plastic sheet to the patient, and admits that such a sheet is known in the prior art. Therefore, Applicant submits that the “material from which the sheet is fabricated” does not comprise a tacky gel material. Applicant submits that Hegwood is more closely analogous to the prior art noted in the present specification than to claims 1 and 10. Applicant further submits that the terms “adhesive” and “tacky gel” are not analogous for the purposes of the claimed invention. Even if, *arguendo*, the plain meaning of such terms would be similar, the Examiner must defer to the definitions of terms given in the specification¹. As the specification distinguishes conventional adhesive from tacky gel, Applicant submits that Hegwood does not disclose every feature of claim 1 and 10, and therefore these claims are patentable over the cited art.

Applicant further submits that claims 2-6 are patentable over the cited art at least by virtue of their respective dependencies from claim 1.

¹ MPEP 2111.01(I), page 2100-38

Claim Rejections - 35 U.S.C. § 103

1. Claims 8 and 12

Claims 8 and 12 are rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Hegwood in view of Kaiser '237. Applicant respectfully traverses.

Applicant submits that Kaiser '237 does not cure the above-noted deficiencies in Hegwood. Hence, Applicant submits that claims 8 and 12 are patentable over the cited art at least by virtue of their respective dependencies from claim 1.

2. Claims 1-6, 9 and 10

Claims 1-6, 9 and 10 are rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Bridge '011 (hereinafter "Bridge") in view of Hegwood. Applicant respectfully traverses.

The Examiner concedes that Bridge does not teach the use of a mounting for a cannula, but asserts that Hegwood cures this deficiency. The Examiner asserts that the combination of these two references would have been obvious to a person having ordinary skill in the art in order to provide an enhanced sealing interface.

The Examiner further asserts that the method of claim 10 would be inherent during normal use and operation of the device resulting from the combined teachings of the cited references.

Regarding independent claims 1 and 10, Applicant submits that, as above, Hegwood does not teach the use of a sheet comprising a tacky gel material. As the Examiner concedes that Bridge does not teach such a mounting either, Applicant submits that the combination of Bridge

and Hegwood does not teach every feature of claims 1 and 10, and these claims are therefore patentable over the cited art. Applicant further submits that claims 2-6 are patentable over the cited art at least by virtue of their respective dependencies.

By this Amendment Applicant amends claim 9 to include the feature that the sheet comprises tacky gel. Applicant submits that as amended, claim 9 is patentable over the cited art for similar reasons as claims 1 and 10.

3. Claim 7

Claim 7 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Hegwood. Applicant submits that claim 7 is patentable over the cited art at least by virtue of its dependency from claim 1.

New Claim

By this Amendment, Applicant adds new claim 13. Applicant submits that new claim 13 has support in the present specification at least at page 6, line 19-25, and at page 8, line 14-17, and is patentable at least by virtue of its dependency from claim 1.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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